

Remarks

Claims 1-4, 6-21, 24-32, 35, 36, and 39-42 are pending in this application. The Applicant herein cancels Claims 9-21, 24-32, 35, 36, 41, and 42 without prejudice or disclaimer of the subject matter therein. Claim 6 and 14 are objected to. The Applicants herein amend Claims 1, 4, 6, and 8 to clarify the claimed subject matter. The Applicant respectfully requests reconsideration and withdrawal of the rejections for the reasons set forth herein.

Copies of the Foreign Documents

A new IDS with copies of WO01/62287, WO00/65058, and WO02/070711 are provided as requested by the Examiner.

Claim Objections

Claim 6 is objected to for an informality, a space is required between “addition” and “and”. The space has been corrected.

Claim 14 is objected to for failing to recite SEQ ID NO:s in the claim. Claim 14 has been cancelled without prejudice or disclaimer of the subject matter therein.

Claim Rejections Under 35 USC § 112

Claims 4, 6, 8, 14, 19-21 and 41 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Without conceding the validity of this rejection, Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Specifically, Applicants have amended claim 4, to recite “T cell epitope” instead of “carrier protein”, thus Claim 4 has antecedent basis in the base claims 1 and 3 and more particularly point out and distinctly claim that which Applicants regard as the subject matter of their invention. The amendment is fully supported by the specification. Specifically, support for the amendments to Claim 4, can be found, for example, at page 15, line 12. Applicants respectfully assert that due to the amendments made to the existing claims, this rejection is now moot. Applicants

cancelled Claims 14, 19-21 and 41, without prejudice or disclaimer of the subject matter therein.

The Examiner suggests Claims 4, 6, 8, 14, 19-21 and 41 are improper Markush groups because of the phrase “selected from the group of”. Without conceding the validity of this rejection, Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Applicants have amended Claims 4, 6, and 8 to include “consisting”. Applicants cancelled Claims 14, 19-21 and 41 without prejudice or disclaimer of the subject matter therein.

In view of the forgoing remarks, the Applicants respectfully submit that they have overcome all grounds of the Examiner's rejection under 35 U.S.C. §112, second paragraph, and that the rejection should be withdrawn.

Claims 1-4, 6-18 and 39-42 stand rejected under 35 U.S.C. § 112, first paragraph. The Examiner correctly states that the specification is enabled for (and is in possession of) an immunogenic composition comprising an IL-13 element as in SEQ ID NO:10 (Immunogen 1) and an IL-13 comprising a number of directed substitutions. However, the Examiner alleges the specification does not reasonably provide enablement for (or comply with the written description requirement for) an immunogenic composition comprising any IL-13 “element”, IL-13 element having “similar conformational shape to native human IL-13”, “sufficient amino acid diversity”, “structurally conservative substitutions”, or “functionally equivalent fragment”.

Without conceding the validity of this rejection, Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Specifically, Applicants have amended Claim 1 to read “An immunogenic composition comprising an IL-13 element, wherein the IL-13 element is Immunogen 1 SEQ ID NO:10, that drives an immune response that recognizes human IL-13 and at least one foreign T-cell epitope.” Remaining Claims 4, 6-8, 39 and 40 depend from base Claim 1. Applicants respectfully assert that due to the amendments made to the existing claims, this rejection is now moot. Applicants cancelled Claims 9-18, 41, and 42, without prejudice or disclaimer of the subject matter therein.

In view of the forgoing remarks, the Applicants respectfully submit that they have overcome all grounds of the Examiner's rejection under 35 U.S.C. §112, first paragraph, and that the rejection should be withdrawn.

Claim Rejections Under 35 USC § 102

Claims 1-3, 6, 7, 9-18, 41 and 42 stand rejected under 35 USC §102(a)(e) as allegedly being anticipated by U.S. Pat. No. 6296843.

Without conceding the validity of this rejection, Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Applicants amended Claim 1 to include the Immunogen 1 SEQ ID NO:10 limitation originally found in claim 21. As stated above, Applicants have amended Claim 1 to read “An immunogenic composition comprising an IL-13 element, wherein the IL-13 element is Immunogen 1 SEQ ID NO:10, that drives an immune response that recognizes human IL-13 and at least one foreign T-cell epitope.” Remaining Claims 2-3, 6, and 7 depend from base Claim 1. Applicants cancelled Claims 9-18, 41, and 42, without prejudice or disclaimer of the subject matter therein.

Claims 1-3, 6, 7, 9-18, 41 and 42 stand rejected under 35 USC §102(b) as allegedly being anticipated by WO99/51643.

Without conceding the validity of this rejection, Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Applicants amended Claim 1 to include the Immunogen 1 SEQ ID NO:10 limitation originally found in claim 21. As stated above, Applicants have amended Claim 1 to read “An immunogenic composition comprising an IL-13 element, wherein the IL-13 element is Immunogen 1 SEQ ID NO:10, that drives an immune response that recognizes human IL-13 and at least one foreign T-cell epitope.” Remaining Claims 2-3, 6, and 7 depend from base Claim 1. Applicants cancelled Claims 9-18, 41, and 42, without prejudice or disclaimer of the subject matter therein.

In view of the foregoing remarks and the claim as amended, the Applicant's respectfully request that the Examiner withdraw her rejections based on 35 USC §102, because the current amended and new claims render these rejections moot.

Claim Rejections Under 35 USC § 103

Claims 1-3, 4, 39 and 40 stand rejected under 35 USC §103(a) as allegedly being unpatentable over U.S. Pat. No. 6296843 or WO99/51643 in view of U.S. Pat. No.6342224.

Without conceding the validity of this rejection, and to further prosecution, the Applicants herein amend the pending claims terms to obviate the asserted basis for this rejection. Specifically, the Applicants have amended Claim 1 to read “An immunogenic composition comprising an IL-13 element, wherein the IL-13 element is Immunogen 1 SEQ ID NO:10, that drives an immune response that recognizes human IL-13 and at least one foreign T-cell epitope.” Remaining Claims 2-3, 4, 39, and 40 depend from base Claim 1. Therefore, the pending claims are not obvious and unpatentable over U.S. Pat. No. 6296843 or WO99/51643 in view of U.S. Pat. No.6342224, because Applicants amended Claim 1 to include the Immunogen 1 SEQ ID NO:10 limitation originally found in Claim 21. The Applicant respectfully asserts that, due to the arguments and amendments made to the existing claims herein, this rejection is now moot.

Claims 1-3, and 6-8 stand rejected under 35 USC §103(a) as allegedly being unpatentable over U.S. Pat. No. 6296843 or WO99/51643 in view of Panina-Bordignon *et al.*

Without conceding the validity of this rejection, and to further prosecution, the Applicants herein amend the pending claims terms to obviate the asserted basis for this rejection. Specifically, the Applicants have amended Claim 1 to read “An immunogenic composition comprising an IL-13 element, wherein the IL-13 element is Immunogen 1 SEQ ID NO:10, that drives an immune response that recognizes human IL-13 and at least one foreign T-cell epitope.” Remaining Claims 2-3 and 6-8 depend from base Claim 1. Therefore, the pending claims are not obvious and unpatentable over U.S. Pat. No. 6296843 or WO99/51643 in view of Panina-Bordignon *et al.*, because Applicants amended Claim 1 to include the Immunogen 1 SEQ ID NO:10 limitation originally found in Claim 21. The Applicant respectfully asserts that, due to the arguments and amendments made to the existing claims herein, this rejection is now moot.

In view of the foregoing remarks and claim amendments, the Applicant respectfully requests that the Examiner withdraw the rejections based on 35 U.S.C. §103.

Non-Statutory Obviousness-Type Double Patenting

Claims 1-3, 6, 7, 9-21, 41 and 42 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatenable over pending claims 1-10 of copending Application No. 10/526,030 (Titled: Injection moulding resin).

Applicants' attorney, Jason Fedon, wishes to thank Examiner Kim for the May 9, 2008, telephonic discussion and for providing further clarification regarding the content of the aforementioned Office Action. During the May 9, 2008, telephonic interview, applicants' attorney noted that:

[1] the copending application the Examiner intended to cite is 10/526,063 (Titled: Vaccine), not 10/526,030 (Titled: Injection moulding resin); and

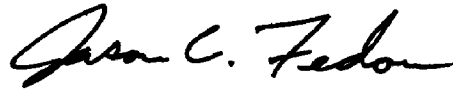
[2] a terminal disclaimer to Application No. 10/526,063 and an amendment of Claim 1 to incorporate Immunogen 1, SEQ ID NO. 10, (from original Claim 21) would remove the provisional obviousness-type double patenting rejections (including: (1) Claims 1, 3, 4, 39 and 40, which stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatenable over claims 1-10 of copending Application No. ~~10/526,030~~ 10/526,063 in view of U.S. Pat. No. 6342224 and (2) Claims 1-3 and 6-8, which stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatenable over claims 1-10 of copending Application No. ~~10/526,030~~ 10/526,063 in view of Panina-Bordignon *et al.*).

Applicants assert that a terminal disclaimer to US Patent Application 10/526,063, is not required in the instant application. In US Patent Application 10/526,063, the Applicants received a Notification to Comply with Requirements for Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures mailed by the office on 10 September 2007, to which Applicants did not respond to by the final deadline of 10 March 2008. Therefore, there is no threat of an unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. As of 19 May 2008, PAIR does not show the updated Abandoned status.

The Applicants reserve the right to prosecute, in one or more patent applications, the canceled claims, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification. If it would expedite prosecution of this application, the Examiner is invited to confer with the Applicants' undersigned attorney. If any additional fees or charges are required by this paper the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

A handwritten signature in black ink, reading "Jason C. Fedon". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

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